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High Production Volume (HPV) Challenge Program

Asphalt, Sulfonated, Sodium Salt
CAS Number 68201-32-1
Revised Test Plan

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ABBREVIATIONS

ACC = American Chemistry Council
API = American Petroleum Institute
BCF = predicted bioconcentration factor
bw = body weight
CPChem = Chevron Phillips Chemical Company LP
EC = Commission of the European Communities
HPV = High Production Volume
IUCLID = International Uniform Chemical Information Dataset
Koc = organic carbon partition coefficient
Kow = n-octanol/water partition coefficient
LC_{50} = lethal concentration (to 50% of animals dosed)
LD_{50} = lethal dose (to 50% of animals dosed)
LOAELs = lowest observed adverse effect levels
NOAELs = no observed adverse effect levels
NOEL = no observed effect level
OECD = Organisation for Economic Cooperation and Development
PAH = polycyclic aromatic hydrocarbons
PDII = primary dermal irritation index
Pow = n-octanol/water partition coefficient
ppm = parts per million
R = asphalt-based complex alkyl aromatic hydrocarbon mixture
SARA = Saturates, Aromatics, Resins, and Asphaltenes
SAS = Asphalt, Sulfonated, Sodium Salt
SIDS = Screening Information Data Set
USEPA = United States Environmental Protection Agency

I. EXECUTIVE SUMMARY

Chevron Phillips Chemical Company LP (CPChem) is committed to fulfilling the High Production Volume (HPV) commitments it made under the U.S. Environmental Protection Agency (USEPA) HPV Challenge Program. As part of this commitment, CPChem has volunteered to assess the health and environmental hazards, including selected physicochemical characteristics of Asphalt, Sulfonated, Sodium Salt (SAS) (CASN 68201-32-1), referred to hereafter as SAS. SAS is a drilling mud additive that is comprised of a diverse distribution of sulfonated alkylaryl hydrocarbon constituents that cross a wide range of molecular weights (500-3000) and are composed of numerous combinations of alkyl and aromatic functional groups with total carbon numbers >25. [redacted].

CPChem has identified data from company proprietary files, peer-reviewed literature, and/or calculated endpoints using widely accepted computer modeling programs.

Physical/Chemical Properties
Physicochemical endpoints for SAS are generally fulfilled by using existing measured data or data calculated by the EPIWIN© computer model.

Environmental Fate/Pathways
A review of the existing data for SAS show that sufficient data are available to characterize the environmental fate. Level III fugacity modeling predicts that releases of SAS to water would remain in water, releases to soil would remain in soil, and releases to air would partition primarily to soil. Ready biodegradation testing showed that SAS is not readily biodegradable and for additional perspective, SAS has low potential for bioaccumulation in the environment as demonstrated by low predicted octanol solubility, log Pow (n-octanol/water partition coefficient), and fish bioconcentration factors. Based on the chemical composition of SAS, it is not expected to undergo abiotic hydrolysis in the environment. No additional testing is needed.

Ecotoxicity
Acute fish, daphnid, and algal endpoints for SAS are fulfilled with valid study data and demonstrate virtually no toxicity to aquatic organisms. No additional testing is proposed for ecotoxicity.

Human Health Effects
Sufficient data are available to characterize the mammalian toxicity of SAS and no additional testing is proposed. SAS has been tested for acute toxicity via the oral route and exhibits a low order of toxicity. The oral administration of sodium sulfonated asphalt to rats by gavage at dose levels of 1000, 500 or 250 mg/kg/day produced no toxicologically significant changes in the parameters measured in a repeated dose study (OECD combined study TG422). The no observed effect level was therefore considered to be 1000 mg/kg/day and no further testing is recommended. In a bacterial reverse mutation assay, (OECD TG471) the test material was considered to be non-mutagenic under the conditions of this test. Likewise, in a chromosomal aberration test (OECD

TG473) the test material was considered to be non-clastogenic to human lymphocytes *in vitro*. As a result, no further genotoxicity testing is recommended. Lastly, in the combined repeated dose and reproductive/ developmental screen (OECD TG422) no effect of treatment was detected on reproduction or offspring development and the no observed effect level for reproductive and developmental toxicity was also considered to be 1000 mg/kg/day. No additional testing for this endpoint is recommended.

Table 1 summarizes the available data for SAS.

Table 1. Matrix of Available and Adequate Data on SAS

Test	SAS
Physical and Chemical Data	
Melting Point	Y
Boiling Point	Y
Vapor Pressure	Y
Partition Coefficient	Y
Water Solubility	Y
Environmental Fate and Pathways	
Photodegradation	Y
Stability in Water (Hydrolysis)	Y
Transport/Distribution	Y
Biodegradation	Y
Ecotoxicity	
Acute/Prolonged Toxicity to Fish	Y
Acute Toxicity to Aquatic Invertebrates	Y
Acute Toxicity to Aquatic Plants (Algae)	Y
Toxicity	
Acute Toxicity (Oral)	Y
Acute Toxicity (Inhalation)	N
Acute Toxicity (Dermal)	N
Repeated Dose	Y
Genetic Toxicity – *in vitro* Gene Mutation	Y
Genetic Toxicity – *in vitro* Chromosomal Aberration	Y
Genetic Toxicity – *in vivo*	N
Reproductive Toxicity	Y
Developmental Toxicity	Y

NOTE:
The data used to characterize the OECD Screening Information Data Set (SIDS) endpoints for substances in this test plan were identified either in company proprietary files, peer-reviewed literature, and/or calculated using widely accepted computer modeling programs. All data were evaluated for study reliability in accordance with criteria outlined by the USEPA (1999). Only studies that met the reliability criteria of "1" (Reliable without restrictions) or "2" (Reliable with restrictions) were used to fulfill OECD SIDS endpoints. Additional data for SAS are also included in the IUCLID (International Uniform Chemical Information Dataset) attached in Appendix I. A more detailed discussion of the data quality and reliability assessment process used in developing this test plan is provided in Appendix II.

II. GENERAL SUBSTANCE INFORMATION

USE: SAS is solely used as an additive for drilling fluids to reduce torque and drag in drilling operations. Under normal operating and use conditions, SAS is not subjected to temperatures greater than 450° F (232°C) as may be expected with asphalts. Exposure to high temperature only occurs in aqueous solution (versus atmospheric conditions) when the SAS-containing drilling fluid is circulated down hole during drilling operations. Upon completion of drilling operations, the drilling fluid is circulated out of the hole and cools as it returns to the surface. The temperature of the drilling fluid being circulated out of the hole ranges from 100-150° F (37-66°C) when it reaches the surface. Under these conditions, fumes are not observed or expected to be emitted from SAS (CPChem Technical Communication, April 2004).

Soltex ® Additive, which uses SAS as the functional ingredient, has been approved for release to the aquatic environment based on data presented in this test plan. This product has been approved by NPDES (National Pollutant Discharge Elimination System) Discharge for oil and gas cutting discharge in Region 9 EPA Gulf Coast Guidelines (40 CFR, Part 435 (a)), and meets OSPAR Convention for the Protection of the Marine Environment in the North-East Atlantic (OSPAR ANNEX 17 (Ref. § 7.4c), Copenhagen: 26 - 30 June 2000).

CHEMISTRY: SAS is a very complex mixture produced by sulfonation of an asphalt-based alkyl aryl hydrocarbon feedstock followed by neutralization of the sulfonated hydrocarbon mixture with sodium hydroxide. This asphalt-based complex alkyl aromatic hydrocarbon mixture ranges in molecular weight from 500-3000 and contains SO_3^- functional groups.

The chemical complexity of SAS comes from the asphalt feedstock, which is naturally variable in composition, and has a wide array of chemical constituents and reactive sites for addition of sulfonic acid functional groups. Asphalt (known as Bitumen in Europe) "is the residuum produced from the non-destructive distillation of crude petroleum at atmospheric pressure and/or under reduced pressures or absence of steam" (Puzinauskas and Corbett, 1978). Asphalts are composed mainly of high-molecular-weight alkylaryl hydrocarbons with high carbon to hydrogen ratios, with carbon numbers > C25, boiling

points > 400 °C, high viscosity, and negligible water solubility and vapor pressure. These asphalt alkylaryl hydrocarbons are a heterogeneous mixture of linear, branched and cyclic, saturated and unsaturated, and aromatic functional groups. Importantly, polycyclic aromatic hydrocarbons (PAH) such as benzo(a)pyrene, which are toxicologically significant, are only present in asphalt feedstock at very low concentrations (Phillips Petroleum Company, 1985). Asphalts contain much larger proportions of high-molecular-weight paraffinic and naphthenic hydrocarbons that are substituted with alkyl groups and ultimately sulfonated, which reduces their potential to exhibit PAH-like toxicity (IARC, 1985 in American Petroleum Institute [API], 2003b).

In practice, the asphalt alkylaryl feedstocks are chemically characterized by a saturates, aromatics, resins, and asphaltenes (SARA) analytical technique. Table 2 describes each of these fractions along with the approximate SARA proportions specifically used in SAS production (Witherspoon, 1962; Phillips Petroleum Company, 1985).

Table 2. Description of SARA Profile of Asphalt Feedstock

[redacted]	Saturates	Consist mainly of long chain saturated hydrocarbons with some branching, alkyl aromatics with long side chains, and cyclic paraffins (napthenes), with molecular weight of 500-1000.
[redacted]	Aromatic*	Consist mainly of substituted benzene and napthenic-aromatic nuclei with alkyl side chain constituents, with molecular weight range of 500-900.
[redacted]	Resins	Consist mainly of heterogeneous polar aromatic compounds with small amounts of oxygen, nitrogen, and sulfur, with molecular weight range of 800-2000. Considered lower molecular weight asphaltenes.
[redacted]	Asphaltenes	Consist mainly of highly condensed aromatic compounds with one or two chromophores containing 4 to 10 fused rings each, with a significant number of alkyl constituents. They have a molecular weight range of 500-1000.

[redacted]

When the alkylaryl hydrocarbons in the asphalt feedstock are sulfonated during production of SAS, they remain intact and the sulfonation process chemically derivitizes them, converting them into alkylaryl sulfonate sodium salts that still contain carbon numbers >C25. The sulfonic acid functional groups form by reaction with double bonds in the hydrocarbons, whether on alkyl chains or aromatic rings. The addition of the sulfonic acid group(s) increases the molecular weight, raising melting points >350 °C and boiling points >500 °C, and further reducing vapor pressure versus asphalt. Sulfonation also increases water solubility, or for the higher molecular weight and more hydrophobic constituents, renders them readily dispersible such that they form stable colloidal dispersions or micelles in water.

Understanding that SAS is a complex chemical mixture of alkylaryl sulfonated isomers becomes critically important when characterizing SAS OECD SIDS endpoints. The physicochemical, environmental, and human health properties of SAS will be a function of the specific constituents in any given sample and should be expected to result in ranges versus discrete endpoints for some physical, chemical, and environmental fate properties.

Additionally the large molecular size of most SAS constituents will reduce their bioavailability.

Note: [redacted].

III. PHYSICOCHEMICAL PROPERTIES

Importantly, SAS are complex heterogeneous mixtures containing many different sulfonated alkylaryl isomers as described above. Therefore, physicochemical properties may vary according to proportions of individual constituents in the sample tested, which results in these substances having ranges rather than discreet melting and boiling points or vapor pressures. Only limited physicochemical testing has been completed for SAS, as summarized in Table 3. Calculations using EPIWIN (USEPA and Syracuse Research Corporation, 2000) are also provided where representative alkylaryl hydrocarbon chemical structures were developed for SAS constituents in the carbon number range of C26-C41. The representative structures are presented in Tables 3a, 4a, and 4b, and are discussed further in subsequent sections.

The physical chemical data provided in Table 3 were experimentally measured or calculated using EPIWIN.

Table 3. Measured and Calculated Physicochemical Properties

Test	SAS
Melting Point	See Table 3a
Boiling Point	>500 °C[3]
Vapor Pressure	Negligible[3]
Kow Partition Coefficient	< 0, 1.1, 3.2, and > 6.2[1] <0[2]
Water Solubility	48.5 wt% @ 20 ± 0.5 °C[4]

[1]TNO Environmental and Energy Research (TNO), 1997.
[2]Chemex Environmental International Limited, 2003.
[3]CPChem internal communication
[4]Safepharm Laboratories Ltd, 2005a.

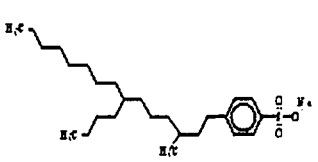
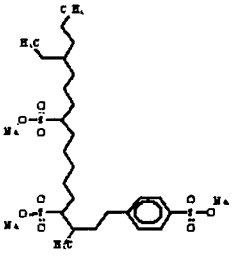
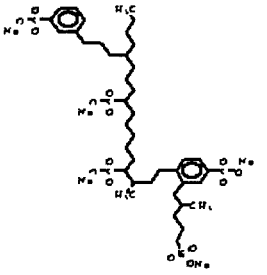
To help further characterize the SAS SIDS physicochemical and environmental fate endpoints and the trends across the expected range of SAS constituents, three

representative sulfonated alkylaryl hydrocarbon chemical structures were developed where carbon number and degree of sulfonation were varied. These are representative of SAS constituents across the carbon number range of C26-C40, as summarized in Table 3a and entered into EPIWIN as follows:

1. A C26 monosulfonated species representing the low end of the molecular weight range of SAS.
2. A C26 trisulfonated species representing a polysulfonated C26 constituent and to illustrate the impact of increasing sulfonation alone versus monosulfonated (#1).
3. A C40 penta-sulfonated species representing the higher end of the carbon number and sulfonic acid group substitution.

In general, increased sulfonation increases boiling points and is expected to increase melting points (EPIWIN can not estimate melting points > 349.84 °C.) Increased sulfonation will also further reduce vapor pressure. Therefore, calculated values for monosulfonated isomers are used for SAS with reporting as greater than "the monosulfonated representative structure" to indicate that there will be a range or that some fraction will decompose.

Table 3a. EPIWIN Physicochemical Data for Representative Structures

Physical and Chemical Data			
Parameter	 (C_{26} H_{43} O_9 S_3 Na_3)	 (C_{26} H_{45} O_3 S Na)	 (C_{40} H_{61} O_{15} S_5 Na_5)
Melting Point	> 349.84 °C [1]	>324.45 °C[1]	>349.84 °C[1]
Boiling Point	916.13 °C [1]	739.46 °C[1]	1276.77 °C[1]
Vapor Pressure	3.9×10^{-23} mmHg at 25 °C [1]	6.02×10^{-18} mmHg at 25 °C [1]	1.75×10^{-33} mmHg at 25 °C [1]
Kow Partition Coefficient	2.32 [2]	6.78 [2]	4.05 [2]

[1] EPIWIN v3.10; MPBPWIN v1.40.
[2] EPIWIN v3.10; calculated using WSKOW v1.40.

These EPIWIN data show that SAS and its surrogates will have high melting point ranges (>349.84 °C), boiling point ranges > 739 °C, and very low vapor pressures. Importantly,

the functional groups in SAS constituents are not labile to hydrolysis. The high degree of sulfonation will significantly increase water solubility and reduce octanol solubility such that SAS constituents will have a very low Kow, where Kow values can range from 2 to 7, and which suggests there is low cause for concern for bioaccumulation in aquatic organisms.

Summary: The weight of evidence supports that adequate data (i.e., Klimisch rating 1 and 2) are available for all physical and chemical endpoints (see Tables 3 and 3a and IUCLID documents).

IV. EVALUATION OF ENVIRONMENTAL FATE DATA

SAS are complex heterogeneous mixtures containing many different sulfonated alkylaryl isomers, as described above. Therefore, environmental fate properties will vary according to the relative proportions of specific functional groups in the sample tested, which results in these substances having ranges rather than discreet environmental fate endpoints such as rate constants, reaction profiles, or partitioning behavior. This complexity especially confounds whole SAS product fugacity modeling since SAS constituents will be subject to differential partitioning depending on the degree of sulfonation and overall carbon content, etc.

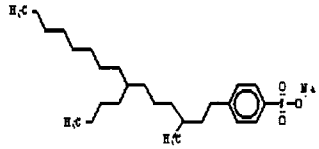
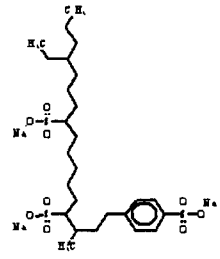
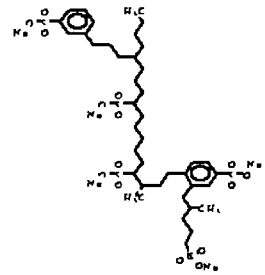
Environmental fate data for SAS were either experimentally measured or estimated using representative structures in EPIWIN, and are provided in Tables 4, 4a, and 4b.

Table 4. Measured and Calculated Results for Environmental Fate and Pathways

Test	SAS
Photodegradation and Atmospheric Oxidation: • OH Half Life	See Table 4a
Stability in Water (Hydrolysis)	No hydrolysis expected
Transport/ Distribution • Fugacity • Estimated Koc: • Estimated BCF:	See Table 4b See Table 4a See Table 4a
Biodegradation	3-6% in 28 days[1] 0% in 56 days[2]

[1]TNO, 1991b.
[2]TNO, 1993

Table 4a. EPIWIN Environmental Fate and Pathways Data for Representative Structures

Physical and Chemical Data			
Parameter	 (C_{26} H_{43} O_9 S_3 Na_3)	 (C_{26} H_{45} O_3 S Na)	 (C_{40} H_{61} O_{15} S_5 Na_5)
Photodegradation and Atmospheric Oxidation:			
• OH Rate Constant	31.5298 x 10^{-12} cm^3/molecule-sec[1]	28.4858 x 10^{-12} cm^3/molecule-sec[1]	45.0897 x 10^{-12} cm^3/molecule-sec[1]
• OH Half Life	4.071 Hrs[1]	4.506 Hrs[1]	2.847 Hrs[1]
Transport/ Distribution			
Fugacity	See Table 4b	See Table 4b	See Table 4b
Estimated Koc:	9.466 x 10^{7} (2)	1.821 x 10^{6} (2)	1 x 10^{10} (2)
Estimated BCF:	70.79[3]	70.79[3]	70.79[3]

[1]EPIWIN v3.10; calculated using AOP Program v1.90.
[2]EPIWIN v3.10; calculated using PCKOC Program v1.66.
[3]EPIWIN v3.10; calculated using BCF Program v2.14.

Summary: The weight of evidence in this test plan supports that no further testing is necessary to meet HPV SIDS endpoints relating to environmental fate. Adequate data (i.e., Klimisch rating 1 and 2) are available for all endpoints; no additional testing is proposed for the USEPA HPV Challenge Program (See Tables 4, 4a, and 4b and IUCLID documents). SAS is expected to be labile and mobile if released to the environment, but will disappear based upon both biotic and abiotic degradation mechanisms. SAS does not pose any bioaccumulation hazard, as described in detail below.

A. Photodegradation – Atmospheric Oxidation

Constituents of SAS are polyaromatic and act as chromophores (which absorb light energy in the 290 nm to 800 nm range where photolytic reactions may result). The degree and rate at which these compounds undergo direct photolysis is a function of the light intensity at site of the SAS molecules. Also, indirect photodegradation may occur in the atmosphere where the SAS constituents interact with photochemically produced hydroxyl radicals, ozone, or nitrogen oxides. Hydrocarbons, such as the alkylaryl hydrocarbons in SAS, react readily with OH^- and NO_3 radicals, and monochromatic and dichromatic compounds react readily with OH^- radicals to undergo degradative reactions (Atkinson, 1990 in API, 2003b). However, due to the fact that SAS have very low vapor pressures, they do not have a tendency to volatilize to air where they can undergo reactions with photosensitized oxygen in the form of hydroxyl radicals (OH^-). As a result, these reactions are not expected to be significant environmental fate processes.

Values for SAS photodegradation and atmospheric oxidation were calculated based upon representative chemical structures using EPIWIN, and are shown in Table 4a. A calculated half-life for SAS of 3 to 5 hours and rate constant of 28×10^{-12} - 45×10^{-12} cubic centimeters (cm^3)/molecule-sec has been estimated using EPIWIN for reaction with hydroxyradicals.

Summary: These results show that SAS may be subject to photodegradation and atmospheric oxidation, and are sufficient for USEPA HPV Challenge Program purposes; no further testing is warranted.

B. Hydrolysis

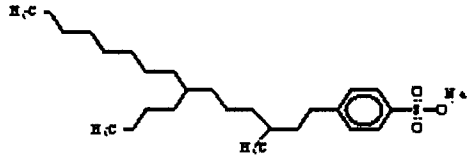
Chemicals that have a potential to hydrolyze include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters (Harris, 1982 in API, 2003a). Because SAS does not contain significant levels of these functional groups, components in SAS are not subject to hydrolysis.

Summary: Components in SAS do not undergo hydrolysis. Existing information is sufficient for USEPA HPV Challenge Program purposes; no further hydrolysis testing is warranted.

C. Chemical Transport and Distribution in the Environment (Fugacity Modeling)

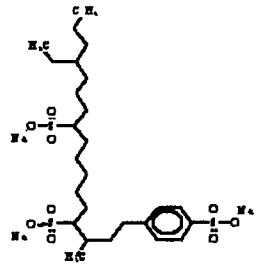
EPIWIN produced the following Level III Fugacity results for the representative structures to SAS:

Table 4b. EPIWIN Level III Fugacity Results for Representative Structures



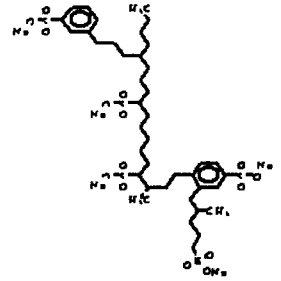
(C_{26} H_{43} O_9 S_3 Na_3)

Compartment	100% to air	100% to water	100% to soil	Equally to each compartment
Air	0.0055%	0.00%	0.00%	0.35%
Water	10.3%	99.5%	5.66%	31.5%
Soil	89.6%	0.00%	94.3%	68.0%
Sediment	0.0557%	0.537%	0.0306%	0.17%



(C_{26} H_{45} O_3 S Na)

Compartment	100% to air	100% to water	100% to soil	Equally to each compartment
Air	5.33%	0.000131%	0.00%	0.444%
Water	2.47%	12.3%	0.00161%	8.2%
Soil	74.7%	0.00183%	100%	33.1%
Sediment	17.5%	87.7%	0.0114%	58.2%



(C_{40} H_{61} O_{15} S_5 Na_5)

Compartment	100% to air	100% to water	100% to soil	Equally to each compartment
Air	0.00%	0.00%	0.00%	0.00246%
Water	3.55%	82.3%	0.156%	15.3%
Soil	95.7%	0.00%	99.8%	81.4%
Sediment	0.763%	17.7%	0.0334%	3.29%

Summary: Results from the Level III fugacity modeling indicate that releases of SAS to water would remain in water, while releases to air would partition primarily to soil. Likewise, releases to soil would remain in soil. Further fugacity modeling is not warranted for the USEPA HPV Challenge Program.

D. Biodegradation and Bioaccumulation

SAS has been tested in two Ready Biodegradation tests in seawater according to proposed EC test guidelines and was not readily biodegradable (3 to 6% in 28 days and 0% in 56 days) in both studies. The results are reliable without restrictions and fulfill the HPV SIDS endpoint for SAS.

In addition, the EPIWIN predicted bioconcentration factor (BCF) for representative structures to SAS were 70.79 and the organic carbon partition coefficients (Koc) were 1.8×10^6 to 1×10^{10}. The BCF should be low, but the BCF QSAR defaults to a low BCF for substances that are expected to be ionized in aqueous media. Overall these results indicate that SAS will be sorptive and poses a low bioaccumulation potential.

Summary: Adequate biodegradation data are available; no additional biodegradability testing is proposed for the USEPA HPV Challenge Program (See Table 4 and IUCLID documents).

V. ECOTOXICITY DATA

Acute fish, daphnid, and algal endpoints for SAS are fulfilled with valid study data. The studies were conducted consistent with relevant OECD and USEPA guidelines that were revised to marine species testing conditions. Marine species were chosen due to the fact that SAS is primarily used in off-shore drilling and therefore, marine species are the most relevant species. As shown in Table 5, SAS is virtually nontoxic to aquatic organisms.

Table 5. Results for Ecotoxicity Endpoints

Test	SAS
Acute/ Prolonged Toxicity to Fish	24- and 48-hr LC_{50} >1,800 mg/L, and 72- and 96-hr LC_{50} = 1,672 mg/L[4, S]
Acute Toxicity to Aquatic Invertebrates	(Daphnia) 96-hr LC_{50} = 420,000 ppm[1,M] (Crustacea) 24-hr LC_{50} = >1000 mg/Liter[5,T] (Crustacea) 48-hr LC_{50} = 380 mg/Liter[5,T]
Acute Toxicity to Aquatic Plants (Algae)	NOEC = 1.0 grams per liter (g/L)[3,K] EC_{50} = 4.0 g/L[3,K] NOEC = 125 mg/L[6,K] ErC_{50} = 390 mg/Liter; EbC_{50} = 240 mg/Liter[6,K]

Test	SAS
Other	Not toxic[2,N] 96-hr LC_{50} = 155,000 ppm (liquid phase bioassay) and 205,000 ppm (suspended particulate phase bioassay)[2,A]

[1]Laboratory Technology, Inc., 1994.
[2]Marine Bioassay Laboratories, 1982.
[3]TNO, 1991a.
[4]Chemex Environmental International Limited, 2002.
[5]Safepharm Laboratories Ltd., 2005b.
[6]Safepharm laboratories Ltd., 2005c.
[A]*Acanthomysis sculpta* (shrimp-like Mysids)
[K]*Skeletonema costatum*
[M]*Mysidopsis bahia* (Mysid shrimp)
[N]*Macoma nasuta* (Mollusca)
[S]*Scophthalmus maximus* (Turbot)

Summary: Adequate aquatic toxicity data are available for SAS; no additional testing is proposed for the USEPA HPV Challenge Program (see Table 5 and IUCLID document).

VI. MAMMALIAN TOXICITY

SAS has been tested for acute toxicity via the oral route and exhibits a low order of toxicity. The oral administration of sodium sulfonated asphalt to rats by gavage at dose levels of 1000, 500 or 250 mg/kg/day produced no toxicologically significant changes in the parameters measured in a repeated dose study (OECD combined study TG422). The no observed effect level was therefore considered to be 1000 mg/kg/day and no further testing is recommended. In a bacterial reverse mutation assay, (OECD TG471) the test material was considered to be non-mutagenic under the conditions of this test. Likewise, in a chromosomal aberration test (OECD TG473) the test material was considered to be non-clastogenic to human lymphocytes in vitro. As a result, no further genotoxicity testing is recommended. Lastly, in the combined repeated dose and reproductive/ developmental screen (OECD TG422) no effect of treatment was detected on reproduction or offspring development and the no observed effect level for reproductive and developmental toxicity was also considered to be 1000 mg/kg/day. No additional testing for this endpoint is recommended.

Table 6. Results for Mammalian Toxicity Endpoints

Test	SAS
Acute Oral	>5,000 milligrams per kilogram (mg/kg) bw (rat – m and f)[1, 2]

Test	SAS
Repeated Dose (oral gavage)	NOEL (males/females) = 1000 mg/kg bw/day[3]
Genetic Toxicity • Bacterial reverse mutation assay • Chromosomal Aberration	 Negative with and without metabolic activation[4] Negative with and without metabolic activation[5]
Reproductive/ Developmental Screen (oral gavage)	Parental NOEL = 1,000 mg/kg bw F1 Offspring NOEL = 1,000 mg/kg bw[3]

[1]Hazleton Laboratories American, Inc., 1985a.
[2]Hazleton Laboratories American, Inc., 1985b.
[3] SafePharm Laboratories Ltd., 2006a
[4] SafePharm Laboratories Ltd., 2006b
[5] SafePharm Laboratories Ltd., 2006c

Summary: Sufficient mammalian toxicity data are available for SAS. No additional testing is proposed for the USEPA HPV Challenge Program (see Table 6 and IUCLID document).

A. Acute Toxicity

SAS demonstrated a low order of toxicity via the oral route of exposure (LD_{50} > 5,000 mg/kg body weight).

Summary: No additional testing is proposed for the USEPA HPV Challenge Program.

B. Repeated Dose Toxicity

The oral administration of sodium sulfonated asphalt to rats by gavage at dose levels of 1000, 500 or 250 mg/kg/day produced no toxicologically significant changes in the parameters measured in a repeated dose study (OECD combined study TG422). The no observed effect level was therefore considered to be 1000 mg/kg/day.

Summary: No additional testing is proposed for the USEPA HPV Challenge Program.

C. Genetic Toxicity/Mutagenicity

In a bacterial reverse mutation assay, (OECD TG471) the test material was considered to be non-mutagenic under the conditions of this test. Likewise, in a chromosomal aberration test (OECD TG473) the test material was considered to be non-clastogenic to human lymphocytes in vitro.

Summary: No additional testing is proposed for the USEPA HPV Challenge Program.

D. Reproductive/Developmental Toxicity

In a combined repeated dose and reproductive/ developmental screen (OECD TG422) no effect of treatment was detected on reproduction or offspring development at doses (oral gavage) of 250, 500, and 1000 mg/kg bw and the no observed effect level for reproductive and developmental toxicity was also considered to be 1000 mg/kg/day.

Summary: No additional testing is proposed for the USEPA HPV Challenge Program.

VII. CONCLUSIONS

As summarized below, adequate data (i.e., Klimisch rating 1 and 2) are available for all the HPV SIDS endpoints.

PHYSICOCHEMICAL DATA. EPIWIN data show representative structures to SAS will have high melting point ranges (>349.84 °C), boiling point ranges > 739 °C, and very low vapor pressures. Importantly, the high degree of sulfonation significantly reduces octanol solubility such that SAS constituents will have a very low Kow, where Kow values can range from 2 to 7, which suggests that there is low cause for concern for bioaccumulation. The weight of evidence supports that adequate data are available for all of the physicochemical endpoints. Therefore, no further testing is proposed for the USEPA HPV Challenge Program.

ENVIRONMENTAL FATE. Values for SAS photodegradation and atmospheric oxidation were calculated based upon representative chemical structures using EPIWIN; no further tested is proposed. Components in SAS do not undergo hydrolysis as they do not contain hydrolysable components. As a result, no further hydrolysis testing is warranted for SAS. Results from the Level III fugacity modeling of representative structures indicate that releases of SAS to water would remain in water and releases to soil would remain in soil while releases to air would partition primarily to soil. Further fugacity modeling is not warranted for the USEPA HPV Challenge Program. Lastly, SAS has been tested in a Ready Biodegradation test and was not readily biodegradable (3 to 6% in 28 days and 0% in 56 days). No further biodegradability testing is proposed. The weight of evidence in this test plan supports that no further environmental fate testing is necessary to meet HPV SIDS endpoints relating to environmental fate; therefore, no additional testing is proposed for the USEPA HPV Challenge Program.

ACUTE AQUATIC TOXICITY. Acute fish, daphnid, and algal endpoints for SAS are fulfilled with valid studies that were conducted consistent with relevant OECD and USEPA guidelines. No further testing is proposed.

ACUTE MAMMALIAN TOXICITY. SAS has been tested for acute toxicity via the oral route. No further acute toxicity testing is proposed.

REPEATED DOSE TOXICITY. SAS has been tested for repeated dose toxicity via the oral route following relevant OECD guidelines (OECD TG422). No further repeated dose toxicity testing is proposed.

GENETIC TOXICITY. SAS has been tested for genetic toxicity in two *in vitro* assays, the Bacterial Reverse Mutation assay (OECD 471) and the Chromosomal Aberration assay (OECD 473). No further genetic toxicity testing is proposed.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY. SAS has been tested for reproductive and developmental toxicity via the oral route according OECD TG422 (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test). No further reproductive or developmental toxicity testing is proposed.

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Appendix II

DATA QUALITY ASSESSMENT

Available environmental, ecotoxicity, and mammalian toxicity studies were reviewed and assessed for reliability according to standards specified by Klimisch et al., (1997), as recommended by the USEPA (1999a) and the OECD (OECD, 2002). The following reliability classification (Klimisch rating) has been applied to each study assessed:

- *1 = Reliable without Restriction* – Includes studies that comply with USEPA- and/or OECD-accepted testing guidelines and were conducted using Good Laboratory Practices (GLPs) and for which test parameters are complete and well documented;

- *2 = Reliable with Restriction* – Includes studies that were conducted according to national/international testing guidance and are well documented. May include studies that were conducted prior to establishment of testing standards or GLPs but meet the test parameters and data documentation of subsequent guidance; also includes studies with test parameters that are well documented and scientifically valid but vary slightly from current testing guidance. Also included in this category were physical-chemical property data obtained from reference handbooks, as well as environmental endpoint values obtained from an accepted method of estimation (e.g., USEPA's EPIWIN estimation program);

- *3 = Not Reliable* – Includes studies in which there are interferences in either the study design or results that provide scientific uncertainty or in which documentation is insufficient; and,

- *4 = Not Assignable* – This designation is used in this dossier for studies that appear scientifically valid but for which insufficient information is available to adequately judge robustness.

Those studies receiving a Klimisch rating of 1 or 2 are considered adequate to support data assessment needs in this dossier. Those key studies selected for inclusion are considered typical of the endpoint responses observed in other studies of a similar nature and design that were identified during our search of the literature.